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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,071	08/22/2003	Philip A. Swain	5673-66690-01	9609

7590 05/01/2006

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EXAMINER

STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/647,071	SWAIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 100-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 100-110 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-99 were canceled in the amendment received February 22, 2005.  
Claims 100-110 are currently pending.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 100-104, drawn to a hapten-carrier conjugate, classified in class 424, subclass 1.57.
  - II. Claims 105-108, drawn to a method of treating nicotine addiction, classified in class 131, subclass 270.
  - III. Claim 109, drawn to a pharmaceutical preparation, classified in class 424, subclass 1.11.
  - IV. Claim 110, drawn to a method of making a hapten-carrier conjugate, classified in class 436, subclass 543.
3. The inventions are distinct, each from the other because of the following reasons:
  - A. Inventions I and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products as claimed have a materially different design. For example, Group III requires an adjuvant which is not required by Group I.

Art Unit: 1639

B. Inventions II and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the processes as claimed have a materially different design, mode of operation, function, and/or effect. For example, the process of Group II requires treating a mammal which is not required by Group IV.

C. Inventions IV (process) and I and III (products) are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make another and materially different product (e.g. a hapten with a magnetic bead carrier). In addition, the products of Groups I and III have been shown to be distinct in section 2A above.

D. Inventions I and III (products) and II (process) are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be utilized to make “anti-hapten” antibodies. In addition, the products of Groups I and III have been shown to be distinct in section 2A above.

Art Unit: 1639

4. Because these inventions are independent or distinct for the reasons given above and
- a. have acquired a separate status in the art in view of their different classification (e.g. class and/or subclass; please refer to section 2 above), and/or
  - b. require a different field of search, and/or
  - c. have acquired a separate status in the art because of their recognized divergent subject matter,
- restriction for examination purposes as indicated is proper. (See MPEP § 808.02).

***Election of Species***

5. This application contains claims directed to the following patentably distinct species of the claimed inventions for Groups I-IV. Election is required as follows.

6. If applicant elects the invention of Group I, the applicant is required to elect a single, specific species from **each** of the following species.

- A. species of "CJ"

Applicant must elect, for the purposes of search, a **single, specific species** of "CJ" which may require the election of a **single, specific species** of "Y" dependent on the species of "CJ" elected.

Claim 100 is generic to the species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent

Art Unit: 1639

and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

7. If applicant elects the invention of Group II, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of hapten-carrier conjugate

Applicant must elect, for the purposes of search, a **single, specific species** of hapten-carrier conjugate.

B. species of administration

Applicant must elect, for the purposes of search, a **single, specific species** of administration.

Claim 105 is generic to the species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

Art Unit: 1639

8. If applicant elects the invention of Group III, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of hapten-carrier conjugate

Applicant must elect, for the purposes of search, a **single, specific species** of hapten-carrier conjugate.

Claim 109 is generic to the species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

9. If applicant elects the invention of Group IV, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of hapten-carrier conjugate

Applicant must elect, for the purposes of search, a **single, specific species** of hapten-carrier conjugate.

Claim 110 is generic to the species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly

Art Unit: 1639

burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

14. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

15. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1639

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to a rejoinder. Further, note that the prohibition against double

Art Unit: 1639

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

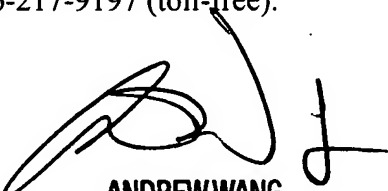
***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS  
April 17, 2006

  
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